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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,896	01/29/2004	Toru Matsumoto	8070-1004	2607

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,896	MATSUMOTO, TORU	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/30/04, 1/29/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising" and "comprise". In addition, the reference numerals should be deleted from the abstract. Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities: On page 7, line 21 of the specification in the brief description of the drawings, the phrase "Fig. 9 shows" should be changed to –Figures 9(a) and (b) show—since figure 9 depicts an (a) and a (b) portion. On page 7, line 23, the phrase "Fig. 10 illustrates" should be changed to –Figures 10 (a), (b), (c) and (d) illustrate—since figure 10 depicts an (a), (b), (c) and (d) portion.

Appropriate correction is required.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Voo et al.

Voo et al teach of a composition or solution that can be used to calibrate electrochemical sensors, which detect analytes in biological fluids such as blood, serum, plasma or urine. The composition comprises a compound containing a heterocycle having nitrogen and sulfur heteroatoms. In particular, the composition comprises the preservatives 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one. 5-chloro-2-methyl-4-isothiazolin-3-one contains both oxo and a halogen directly bound to the heterocycle, and 2-methyl-4-isothiazolin-3-one contains oxo directly bound to the heterocycle. See lines 60-67 in column 1 and lines 1-4 in column 2 of Voo et al. Voo et al teach that electrochemical sensors are subject to decomposition caused by microbes present in the solutions to which the sensor comes into contact such as a calibration solution. The microbes cause detrimental effects because of the acidic products formed. These acidic products serve to change the pH in the vicinity of the sensor, thus affecting the performance of the electrodes in the sensor. See lines 56-67 in column 2 and line 1 in column 3 of Voo et al. The composition taught by Voo et al serves to prevent the growth of microbes in the vicinity of electrochemical sensors so as to avoid the detrimental effects to the performance of the electrodes in the sensors caused by an acidic pH produced by the microbes.

7. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Shin et al.

Shin et al teach of a solution for increasing the accuracy and effective life span of an electrochemical sensor system. The solution can serve as a calibrating solution for an

electrochemical sensor. The solution comprises among other components 2-methyl-4-isothiazolin-3-one hydrochloride, which is a compound containing a heterocycle having a nitrogen and a sulfur heteroatom. This compound contains oxo directly bound to the heterocycle. See paragraph nos. 0005-0007 and 0039-0040 in Shin et al.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art on pages 1-3 and in Figure 1 of the instant application in view of Voo et al. For a teaching of Voo et al, see previous paragraphs in this Office action.

Applicant admits on pages 1-3 of the instant specification that an electrochemical sensor such as that depicted in Figure 1 of the instant application is known. Such an electrochemical sensor comprises a substrate 6 on which is formed an electrode 10. Layered on top of the electrode 10 are a binding layer 7, an enzyme layer 8 and a permeation-limiting layer 9. Therefore, the sensor comprises multiple organic material layers in addition to the enzyme layer,

which are responsible for various functions to improve the performance and reliability of the sensor. Applicant admits that it is conventional to store such an electrochemical sensor in a storage solution and to calibrate such a sensor with a calibration solution. However, problems with the sensors have been encountered when used in conjunction with such storage or calibration solutions. These problems include the growth of a mold or microorganisms in the solutions that cause an inactivation of the enzyme in the sensor and a detachment of the film constituting the sensor, leading to deterioration of sensor function and pH reduction of the storage solution. Applicant admits that in order to solve this problem, some of the prior art has used antibacterial and antiseptic materials such as sodium azide to prevent the growth of microorganisms. However, this type of material oxidatively decomposes and damages the enzyme used in the sensor. Therefore, it is desirable to solve this problem with the storage and calibration of electrochemical sensors in some other way. Applicant fails to teach that it is known in the art to store or calibrate electrochemical sensors in solutions that contain a heterocycle having nitrogen and sulfur heteroatoms.

Based upon the combination of Applicant's admitted prior art in the instant application and Voo et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to inhibit the growth of microorganisms in an electrochemical sensor subjected to a storage solution or a calibration solution by incorporating into the organic layers of the sensor a compound containing a heterocycle having nitrogen and sulfur heteroatoms, such as the composition taught by Voo et al, since Voo et al disclose that such a composition serves to prevent the growth of microbes in the vicinity of electrochemical sensors so as to avoid the

detrimental effects to the performance of the sensors caused by the microbes without oxidatively decomposing or damaging the enzymes in the sensors.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Abel et al who teach of reagent solutions for calibrating electrochemical biosensors.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 28, 2005

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700